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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/591,658      | 08/15/2007  | Makoto Yuasa         | 295973US0PCT        | 3124             |

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| EXAMINER |
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FIERRO, ALICIA LORETTA

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

4121

|                   |               |
|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

12/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
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|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/591,658 | <b>Applicant(s)</b><br>YUASA ET AL. |  |
|                              | <b>Examiner</b><br>ALICIA L. FIERRO  | <b>Art Unit</b><br>4121             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-10 and 12-19 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 3-10 and 12-19 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1, 3-10, and 12-19 are pending in the current application according to the *Amendments to the Claims*, filed August 15, 2007. Furthermore, according to this *Amendment*, claims 1, 3-6, 10, 13, 17, and 19 were amended and claims 2 and 11 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/JP2004/002750, filed 8/15/07.

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claim(s) 1, 3-10, 13-16, drawn to a product and a drug comprising said product.

Group II: Claim(s) 12, drawn to a process for making the product of Group I.

Group III: Claim(s) 17-19, drawn to methods of using the product of Group I to treat various conditions.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied "where a group of inventions is claimed in one and the same international application, the requirement of unity referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship

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among those inventions involving one or more of the same or corresponding special technical features.”

The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art so linked as to form a single general inventive concept. The metalloporphyrin complex-embedding niosome of Claim 1 is the shared feature of Groups I-III. This complex as claimed is a “therapeutic agent for inflammation” (Claim 16). In UK Patent Application GB2189457A, which was provided by applicant, L’Oreal teaches the use of an anti-inflammatory substance incorporated into a niosome for therapeutic use. Further, Cuzzocrea teaches the use of a metalloporphyrin complex as an anti-inflammatory agent (abstract and page 174, column 2, lines 7-16). One of ordinary skill in the art would be motivated to add the metalloporphyrin complex taught by Cuzzocrea into a niosome. It is stated in the “Background Art” section of the instant specification that administration of metal porphyrin complexes alone into a living body presents “problems from the viewpoint of safety and effects.” Niosomes are known to be effective for encapsulating drugs, keeping the structure of the molecule in tact and allowing for a controlled release of the compound inside.. As a result, as currently presented, claim 1 lacks a general inventive step and therefore does not possess a special technical feature and, as such, Groups I-III lack a special technical feature.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature

common to Groups I-III is a metalloporphyrin complex-embedding niosome, which is claimed to have anti-inflammatory properties. The prior art teaches that metalloporphyrin complexes have anti-inflammatory mechanisms and that anti-inflammatory therapeutic agents can be incorporated into niosomes. Therefore, there is not a special technical feature present which links the claims as defined by PCT Rule 13.2.

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

#### ***Election of Species***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. As an additional requirement, with the election of any one of **Groups I-III**, an election of species of a particular compound is also required. In order for this election to be considered fully responsive to this requirement, the election **must include**:

#### **Groups I-III:**

- a) the **name** and **structure** of one species of the instantly claimed compound. This includes the election of a specific **metal (M)**, **nonionic surfactant**, and **cholesterol**.
- b) the **location** of the species (a) within the claims or (b) within the specification,
- c) the **claims** that read on the elected species,

d) a **definition** of the exact substitutions,

e.g. R<sub>1</sub> is hydrogen, X is oxygen, etc...

**Group III:**

a) election of a **single disease** to be treated

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

Claims 5-9 and 17-19 correspond to various structurally different compounds of formula I, II, or III.

The following claim(s) are generic: 1, 3-4, 10, 12-16.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the core structure of

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the generic compound fails to overcome that of the prior art. Additionally, for example, a compound of Formula II where  $R_{18}$  is an N-lower-alkylpyridyl group is structurally different than a compound of formula II where  $R_{18}$  is an N-lower-alkylimidazolyl group. Therefore, these two compounds are different species or lack the same core structure or special technical feature.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALICIA L. FIERRO whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Friday 7:30-5:00 with alternating Fridays off.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALF

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4121